

094444-09401

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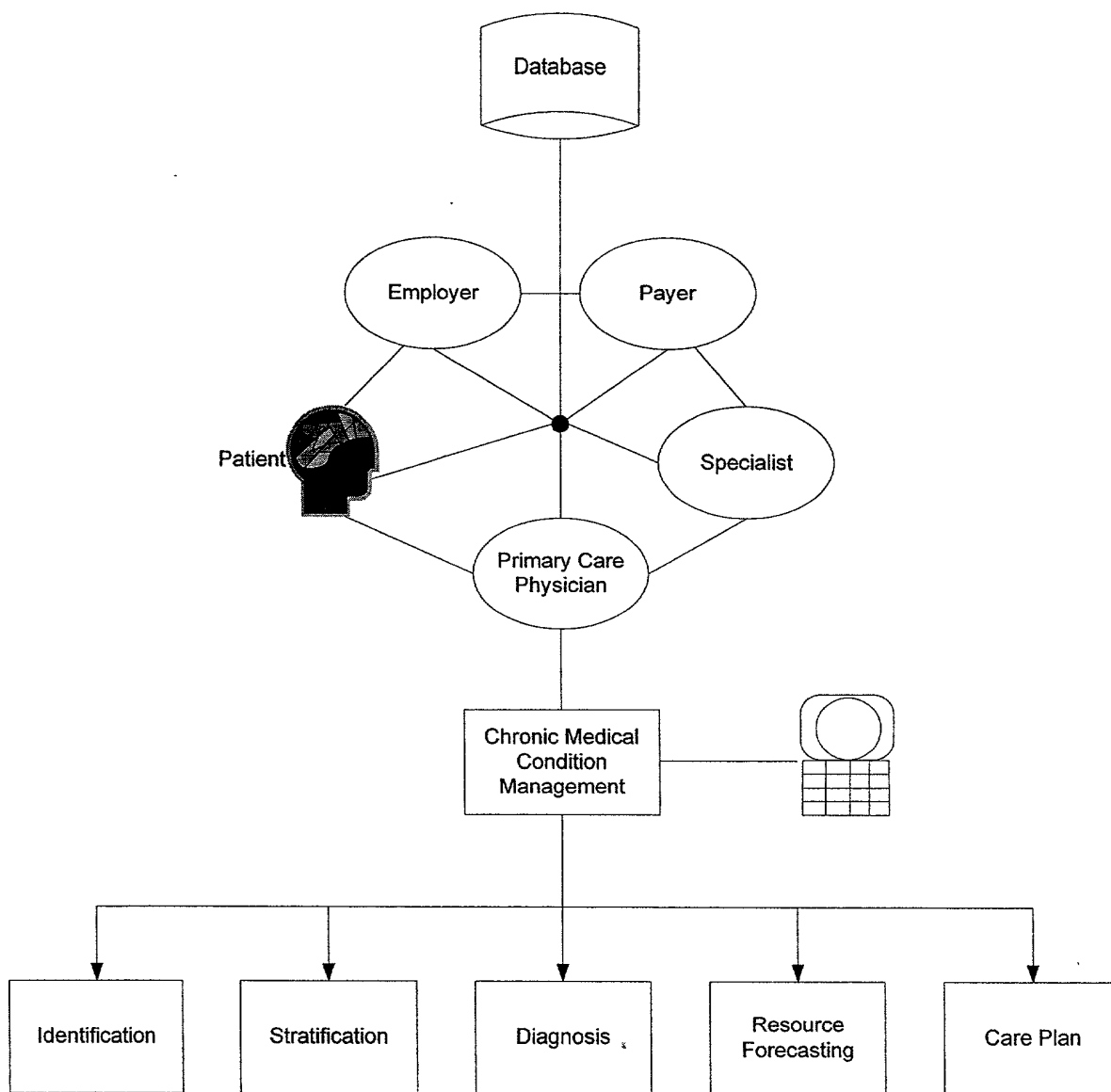


FIG. 1

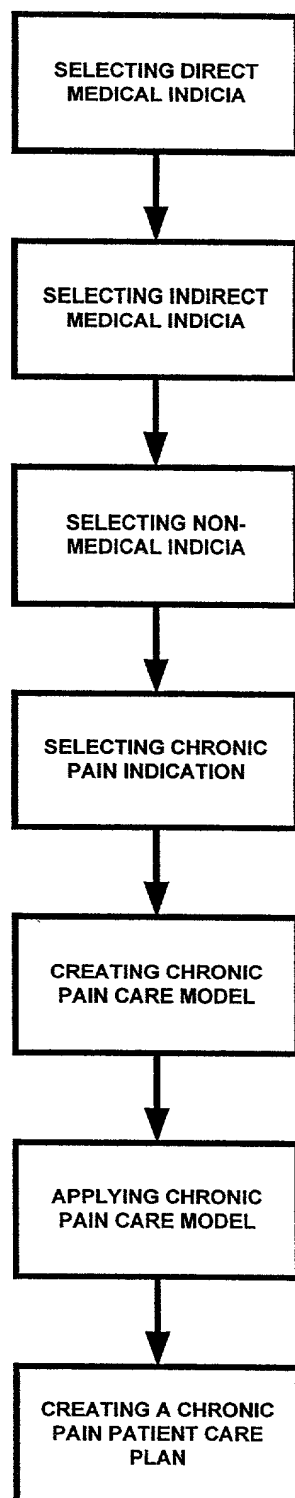


FIG. 2

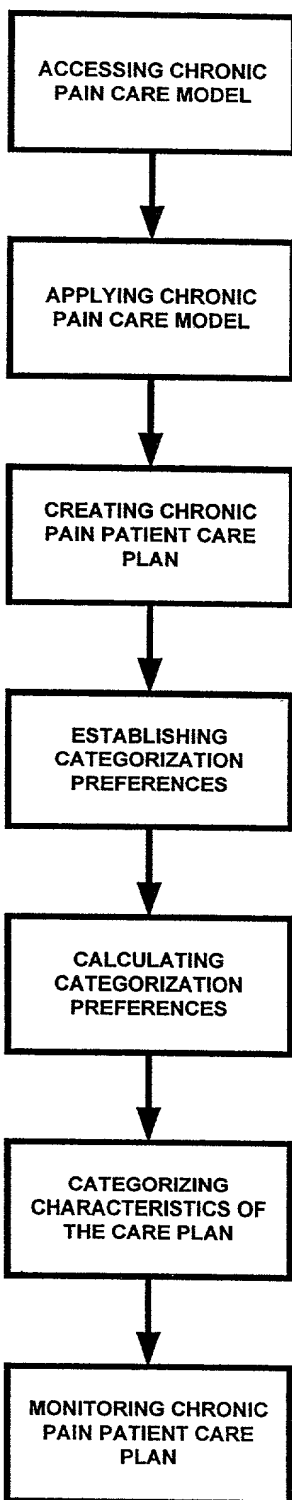


FIG. 3

FIG. 4

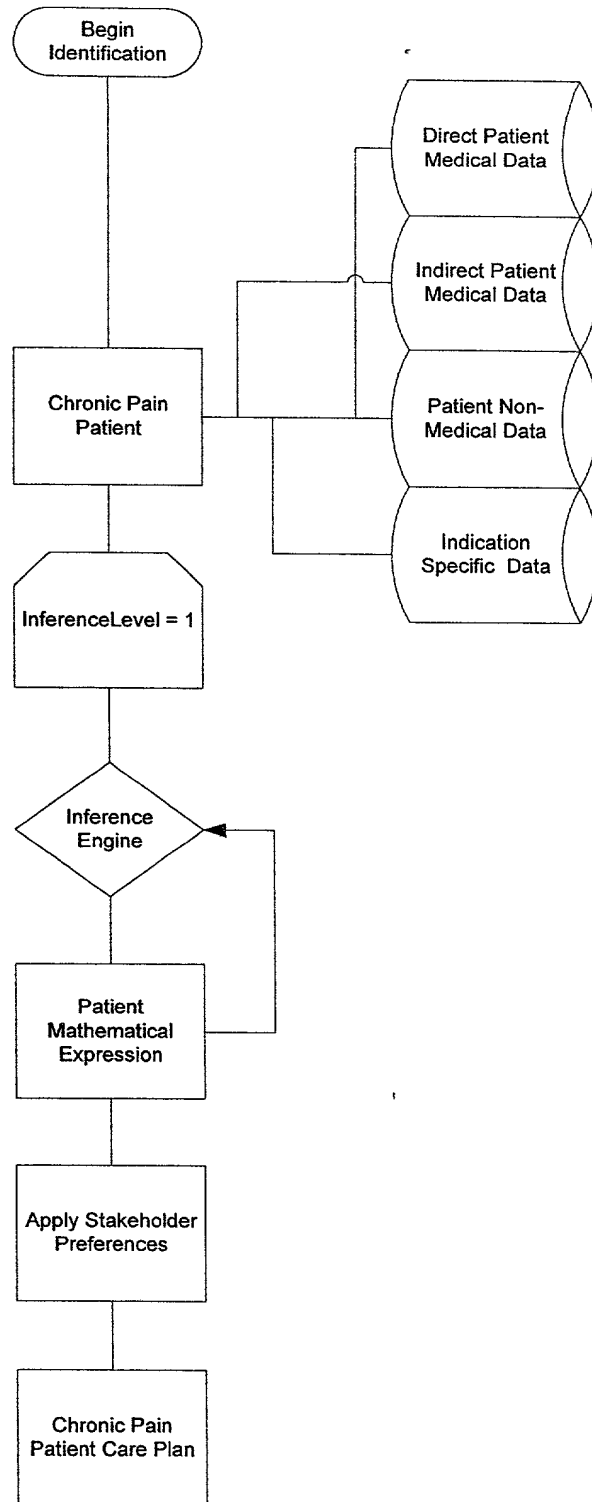


FIG. 4

Direct Medical Indicia	Remarks
1. ICD-9-CM "Specific" Lumbar Spine Diagnoses Code.	The Direct Medical Indicia example used in this document relates to the lumbar spine pain indication. For this example there is a specific ICD-9-CM diagnostic code relating to the underlying injury. The presence of this (and similar codes for other pain indications) is a significant indicator for the presence of pain.
2. ICD-9-CM "Non-specific" Generalized Pain Syndrome Diagnoses Codes.	It is common for pain to be characterized in a "non-specific" manner by providers who are not pain treatment specialists. However, this code indicates the presence of pain, and is an important indicator.
3. ICD-9-CM Diagnosis Code Identifying a Comorbidity Commonly Associated with Lumbar Spine Injury.	Chronic pain patients typically have an assortment of health problems. Patterns or clusters of these other health issues can be identified in the data, and more will be learned from the inductive learning capabilities of the chronic condition management system.
4. ICD-9-CM "Other" Medical Condition Diagnostic Code Clearly Attributing the Condition to a Diagnosis Commonly Associated with Chronic Pain.	There are numerous known medical conditions for which pain is an associated symptom. Often, these conditions are reflected in the medical data, while the pain condition is not specifically coded. Identifying the presence of these codes is a significant indicator for the presence of a pain condition.
5. ICD-9-CM Procedure Codes Indicating the Condition is Related to a Known Acute Pain Condition (e.g. post-operative surgical pain).	There is a commonly accepted list of known ICD-9-CM procedure codes associated with the treatment of acute pain. The presence of one or more of these codes is a significant indicator for the presence of acute pain.
6. CPT Codes Indicating the Condition is Related to a Known Acute Pain Condition (e.g. post-operative surgical pain).	There is a commonly accepted list of known physician services (CPT) codes associated with the treatment of acute pain. The presence of one or more of these codes is a significant indicator for the presence of acute pain.
7. ICD-9-CM Procedure Codes Relating to Lumbar Spine Care.	There is a commonly accepted list of known ICD-9-CM procedure codes associated with lumbar spine care. It is commonly accepted that pain is often concomitantly associated with lumbar spine care. The presence of one or more of these codes is an indicator for the potential presence of lumbar spine pain.
8. ICD-9-CM Procedure Codes Relating to Lumbar Spine Pain.	There is a commonly accepted list of known ICD-9-CM procedure codes associated with the treatment of lumbar spine pain. The presence of one or more of these codes is a significant indicator for the presence of lumbar spine pain.
9. ICD-9-CM Procedure Codes Relating to Lumbar Spine Pain Establishing a Pattern of Chronicity (time and homogeneity).	It is assumed that a pattern of specific treatment occurring continuously over the course of ≥ 91 days tends to indicate a pattern of chronicity.

FIG. 5a

Direct Medical Indicia	Remarks
10. CPT Codes Identifying Lumbar Spine Care-related Procedures.	There is a commonly accepted list of known physician service (CPT) codes associated with lumbar spine care. It is commonly accepted that pain is often concomitantly associated with lumbar spine care. The presence of one or more of these codes is an indicator for the potential presence of lumbar spine pain.
11. CPT Codes Identifying Lumbar Spine Pain-related Procedures.	There is a commonly accepted list of known physician service (CPT) codes associated with the treatment of lumbar spine pain. The presence of one or more of these codes is a significant indicator for the presence of lumbar spine pain.
12. CPT Codes Identifying Lumbar Spine Pain-related Procedures Establishing a Pattern of Chronicity.	It is assumed that a pattern of specific treatment occurring continuously over the course of ≥ 91 days tends to indicate a pattern of chronicity.
13. Drug Prescription Codes for opioid, non-steroidal or muscle relaxant indicating dosage, frequency, length of time, combinations consistent with spine pain treatment.	There is a commonly accepted list of nationally recognized drug codes associated with the treatment of lumbar spine pain. The presence of one or more of these codes is an indicator for the presence of lumbar spine pain. The predictive power of prescription drug codes significantly increases as such drug codes are found in combination with one another.
14. Drug Prescription Codes for opioid, non-steroidal or muscle relaxant indicating dosage, frequency, length of time, combinations identifying patient as being at risk of developing a chronic lumbar pain condition.	A patient's drug treatment regimen is significantly related to their propensity to later develop a chronic pain condition.
15. Drug Prescription Codes for opioid, non-steroidal or muscle relaxant indicating dosage, frequency, length of time, combinations consistent with chronic spine pain treatment.	It is assumed that a pattern of specific treatment occurring continuously over the course of ≥ 91 days tends to indicate a pattern of chronicity.
16. Emergency Room Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Condition	A patient's frequent use of emergency room services is an indicator of an uncontrolled or "spiking" medical condition. It is common for lumbar spine patients who are experiencing associated severe pain, to make use of emergency room services, particularly those associated with pain control. This is a significant indicator of the presence of uncontrolled pain.

FIG. 5b

Direct Medical Indicia	Remarks
17. Emergency Room Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Pain Condition	A patient's frequent use of emergency room services is an indicator of an uncontrolled or "spiking" medical condition. It is common for lumbar spine patients who are experiencing associated severe pain, to make use of emergency room services, particularly those associated with pain control. This is a significant indicator of the presence of uncontrolled pain.
18. Emergency Room Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Establishing the Chronicity of a Lumbar Spine Pain Condition (time and pattern or homogeneity)	It is assumed that a pattern of specific treatment occurring continuously over the course of ≥ 91 days tends to indicate a pattern of chronicity.
19. Hospitalizations Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Condition	"Days in hospital" is an indicator of a patient's uncontrolled or "spiking" medical condition, and can relate to severity level of that patient's medical condition. Lumbar spine patients who are experiencing associated severe pain, are sometimes hospitalized for that condition. This is a significant indicator of the presence of uncontrolled pain.
20. Hospitalizations Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Pain Condition	"Days in hospital" is an indicator of a patient's uncontrolled or "spiking" medical condition, and can relate to severity level of that patient's medical condition. Lumbar spine patients who are experiencing associated severe pain, are sometimes hospitalized for that condition. This is a significant indicator of the presence of uncontrolled pain.
21. Hospitalizations Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Establishing the Chronicity of Lumbar Spine Pain Condition (time and pattern or homogeneity)	It is assumed that a pattern of specific treatment occurring continuously over the course of ≥ 91 days tends to indicate a pattern of chronicity.
22. Physician Office Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Condition	Frequency of "physician office visits" is an indicator of a patient's uncontrolled or "spiking" medical condition, and can relate to severity level of that patient's medical condition. Lumbar spine patients who are experiencing associated severe pain often seek in-office physician care for that condition. This is a significant indicator of the presence of uncontrolled pain.

FIG. 5c

Direct Medical Indicia	Remarks
23. Physician Office Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Indicating a Lumbar Spine Pain Condition.	Frequency of "physician office visits" is an indicator of a patient's uncontrolled or "spiking" medical condition, and can relate to severity level of that patient's medical condition. Lumbar spine patients who are experiencing associated severe pain often seek in-office physician care for that condition. This is a significant indicator of the presence of uncontrolled pain.
24. Physician Office Visits (with ICD-9-CM, CPT or Drug Codes, or test results) Establishing the Chronicity of a Lumbar Spine Pain Condition (time and pattern or homogeneity of complaint).	Frequency of "physician office visits" is an indicator of a patient's uncontrolled or "spiking" medical condition. Lumbar spine patients who are experiencing associated severe pain often seek in-office physician care for that condition. This is a significant indicator of the presence of uncontrolled pain.
25. Rehabilitation or Palliative Care ICD-9-CM Procedure Codes.	Pain patients often receive rehabilitation or palliative care services as a part of their proscribed treatment regimen.
26. Telephone Consultation (with documentation relating to lumbar spine pain condition)	Frequency of "telephone consultations" with a care provider is an indicator of a patient's uncontrolled or "spiking" medical condition. Lumbar spine patients who are experiencing associated severe pain often contact their care for that condition. This is an indicator of the presence of uncontrolled pain.
27. Coded Trauma (related test result, procedure, etc.).	Trauma is a precipitating factor for certain pain indications.

FIG. 5d

Direct Medical Indicia Drug Product	Maximum Recommended Daily Dose (Adult)	Chronic Pain Indicators
Over The Counter Non-Narcotic Analgesic Agents		
Acetaminophen (Tylenol)	12 tabs	12 tabs ≥91 days
Aspirin 325mg	18 tabs	18 tabs ≥91 days
ibuprofen 200mg (Motrin)	16 tabs	16 tabs ≥91 days
Salicylate Agents		
Salsalate 500mg (Disalcid)	6 tabs	6 tabs ≥91 days
Diflunisal 500mg (Dolobid)	3 tabs	3 tabs ≥91 days
Opioid and Related Analgesic Agents		
APAP/Propoxyphene Napsylate 100 (Darvocet-N 100)	6 tabs	6 tabs ≥91 days
APAP/Oxycodone 5/325 (Percocet)	12 tabs	12 tabs ≥91 days
ASA/Oxycodone 5/325 (Percodan)	18 tabs	18 tabs ≥91 days
APAP/Oxycodone 5/500 (Tylox)	8 tabs	8 tabs ≥91 days
APAP/Hydrocodone 5/500 (Vicodin)	8 tabs	8 tabs ≥91 days
APAP/Hydrocodone 10/650 (Lorcet)	6 tabs	6 tabs ≥91 days
APAP/Hydrocodone 2.5/500 (Lortab)	8 tabs	8 tabs ≥91 days

FIG. 6a

Direct Medical Indicia Drug Product	Maximum Recommended Daily Dose (Adult)h	Chronic Pain Indicators
APAP/Codeine 30/300 (Tylenol-3)	12 tabs	12 tabs ≥91 days
Non-Steroidal Anti-inflammatory Drugs (NSAIDs)		
Celecoxib (Celebrex)	4 caps	4 caps ≥91 days
Diclofenac 100mg ER (Voltaren XR)	2 tabs	2 tabs ≥91 days
Etodolac Extended Release 400mg (Lodine XL)	3 tabs	3 tabs ≥91 days
Naproxen Controlled Release 500mg (Naprelan)	2 tabs	2 tabs ≥91 days
Nabumetone 500mg (Relafen)	4 tabs	4 tabs ≥91 days
Muscle Relaxants		
Carisoprodol (Soma)	4 tabs	4 tabs ≥91 days
Chlorzoxazone (Paraflex)	12 tabs	12 tabs ≥91 days
Cyclobenzaprine (Flexeril)	6 tabs	6 tabs ≥91 days
Diazepam 5mg (Valium)	8 tabs	8 tabs ≥91 days
Metaxalone (Skelaxin)	8 tabs	8 tabs ≥91 days
Methocarbamol 500 (Robaxin)	8 tabs	8 tabs ≥91 days
Orphenadrine Citrate (Norflex)	2 tabs	2 tabs ≥91 days

FIG. 6b

Indirect Medical Indicia	Measure	Remarks
1. Physician Office Visits a. Documented reason for visit b. Physician specialty associated with visit c. Time period establishing chronicity	a. Associated ICD-9-CM or CPT code. b. Medical record notation. c. Associated time period, either multiple visits within an associated period of time; or pattern of visits showing elapsed period of time (e.g. ≥ 91 days).	Chronic pain patients frequently visit the physician office, for pain related reasons as well as for complaints of non-specific origin.
2. Emergency Room Visits a. Reason for visit b. Time period establishing chronicity	a. Associated ICD-9-CM or CPT code. b. Associated time period, either multiple visits within an associated period of time; or pattern of visits showing elapsed period of time (e.g. ≥ 91 days months).	Chronic pain patients frequently present to the ER for pain related reasons as well as for complaints non-specific in origin.
3. Drug Therapy a. Drug prescription b. Drug combinations c. Dosing levels d. Prescription patterns e. Time period establishing chronicity f. Pattern of substance abuse	a. Drug code for drugs (e.g. anti-inflammatory, antidepressant, muscle relaxant, opioid) associated with pain symptom treatment. b. Drug codes, when used in combination, tend to indicate presence of pain. c. Dosing level consistently high. d. Multiple prescribers. e. Associated time period establishing elapsed period of time (≥ 91 days). f. Evidence of drug over use or use of illegal drugs.	Prescription and non-prescription drug use is a common indicator of chronic pain. Such drugs are often provided to patients from a variety of sources in an uncoordinated manner, or without the development of a patient plan of care.
4. Telephone Consults a. Documented reason for call b. Frequency of calls c. Pattern of calls d. Time period establishing chronicity	a. Notation in medical record, associated code if possible. b. Calls outside the defined range of frequency for a typical patient. c. Clustered calls with a defined time period. e. Associated time period establishing elapsed period of time (≥ 91 days).	Chronic pain patients often demand more attention from their caregivers than the general population, for symptom – specific as well as for non-symptom specific reasons.

FIG. 7a

Indirect Medical Indicia	Measure	Remarks
5. Primary Diagnosis	ICD-9-CM diagnostic code associated with pain condition or trauma, or with a disease known to have associated pain condition.	Chronic pain can be identified through diagnostic codes two ways: the pain can be a condition associated with a disease state such as diabetes (indirect), or it can be the primary reason for the pain condition such as low back pain (direct).
6. Co-Morbidities	ICD-9-CM diagnostic code associated with conditions known to occur with chronic pain.	Certain co-morbidities are known to be associated with chronic pain.
7. Hospitalizations <ul style="list-style-type: none"> a. Time period establishing chronicity b. Admitting diagnosis c. Procedures performed 	<ul style="list-style-type: none"> a. Associated time period either multiple visits within an associated period of time, or pattern of visits showing elapsed period of time (e.g. ≥ 91 days). b. Associated ICD-9-CM diagnostic code. c. Pattern of ICD-9-CM and CPT procedure codes. 	Certain chronic pain patients are frequently hospitalized, either to treat spikes in pain, or to receive back-related procedures.
8. Evidence of trauma <ul style="list-style-type: none"> a. Diagnostic test associated with trauma 	<ul style="list-style-type: none"> a. Test results such as x-ray, contained in medical record. 	Numerous chronic pain indications are trauma-related in origin (e.g. CRPS).
9. Evidence of palliative or rehabilitation care <ul style="list-style-type: none"> a. Documented procedure b. Pattern of care c. Time interval establishing chronicity 	<ul style="list-style-type: none"> a. ICD-9-CM procedure codes associated with palliative or rehabilitation care. b. Evidence of care seeking behavior relating to combination of providers. c. Associated time period, either multiple visits within an associated period of time; or pattern of visits showing elapsed period of time (e.g. ≥ 91 days). 	Chronic pain patients receive a variety of physical therapy, chiropractic services, acupuncture therapy and other similar types of services to treat their condition.

FIG. 7b

Non-Medical Indicia	Remarks
1. Patient Self-Assessment - Pain Significantly Interferes with Life Activities	Patient self-assessment is one important and relevant perspective to measure the patient's perceptions relative to the impact the pain is having upon the quality of their life. This data is critical in stratifying patients; for example, a high score could trigger "a high need for treatment immediacy" category.
2. Patient Self-Assessment - High Pain Intensity Rating	This data is critical in stratifying patients; for example, a high score could trigger "a high need for treatment immediacy" category.
3. Patient Self-Assessment - Intense and Multiple Pain Descriptors	This data is critical in stratifying patients; for example, a high score could trigger "a high need for treatment immediacy" category.
4. Patient Self-Assessment - High Impact of Pain on Mood	This data point is also a quality of life indicator, measuring patient's perception of how pain alters personality.
5. Patient Self-Assessment - Low Family Support	Family support is a key indicator of treatment success. It also has an impact on the type of treatment that a provider will prescribe (For example, certain treatments are enhanced through the encouragement of family.)
6. Patient Self-Assessment - High Impact of Pain on Ability to Work	This is a data point that will be of particular interest to the payer and employer. It also can be relevant in determining the type and intensity of treatment.
7. Patient Self-Assessment - High Impact of Pain on Health Status	This data point is an important quality of life indicator.
8. Patient Self-Assessment - Downward Health Trend	This data point is an important quality of life indicator.
9. Patient Self Assessment - Depression	Many chronic pain patients suffer from depression (accounting for up to 40% of overall health care costs associated with the treatment of low back.) It is a key chronic pain indicator, and will be a determining factor in course of treatment.
10. Patient Self-Assessment - Low Life Satisfaction Score	This data point is an important quality of life indicator.
11. Patient Self-Assessment, or Family Assessment - Poor Community Support Structure	Community support is a key indicator of treatment success.
12. Patient Self-Assessment - Low Job Satisfaction Score	This data point is an important quality of life indicator.

FIG. 8a

Non-Medical Indicia		Remarks
13. Patient Self-Assessment, or Family Assessment - Lack of Daytime Distractions		This data point is a predictor of treatment success.
14. Patient is a Smoker		Smoking complicates the delivery of health care services, has a direct relationship to health outcomes, and is a significant driver of health care costs.
15. Other Behavior Characteristics <ul style="list-style-type: none"> • Current • Past* 		This is relevant to predict treatment success, to determine course of treatment, and as a stratification indicator.
16. Patient Matches Personality/Psychological Risk Profile		Personality characteristics are strong indicators of treatment success, and also provide guidance in determining choice of treatment.
17. Pending Litigation Relating to Injury		The existence of a pending lawsuit has a measurable relationship to treatment outcome, particularly as it relates to length of treatment.
18. Patient is Overweight by more than 25% of Normal Weight		Weight relates to treatment choice, treatment outcome and to health care complications (which relate to overall health care treatment costs.)
19. Patient's Job is in a High Work Risk Category		Patients in certain high-risk work categories, such as trucking and heavy industry, have a much higher incidence of low back injuries and other chronic pain indications.
20. Patient Involved in Recent or Pending Divorce		A patient's marital status relates to state of being, which is related to how well a patient will respond to treatment. It also relates to stress, which increases a patient's overall risk for an adverse health event.
21. Other Demographic Indicators: <ul style="list-style-type: none"> * Age * Race/ethnicity * Religion * Economic status * Gender 		Certain demographic factors, such as those listed, have a direct relationship to treatment choice, treatment outcome and health care complications (which relate to overall health care treatment costs.)
22. Open Workers' Compensation Claim		The existence of an open workers' compensation claim is a significant predictor of treatment outcome, particularly as it relates to length of treatment. It is also a variable an employer is interested in tracking.
23. Patient has Hired an Attorney for Representation on a Work-related Injury		The existence of an attorney has a measurable relationship to treatment success.

FIG. 8b

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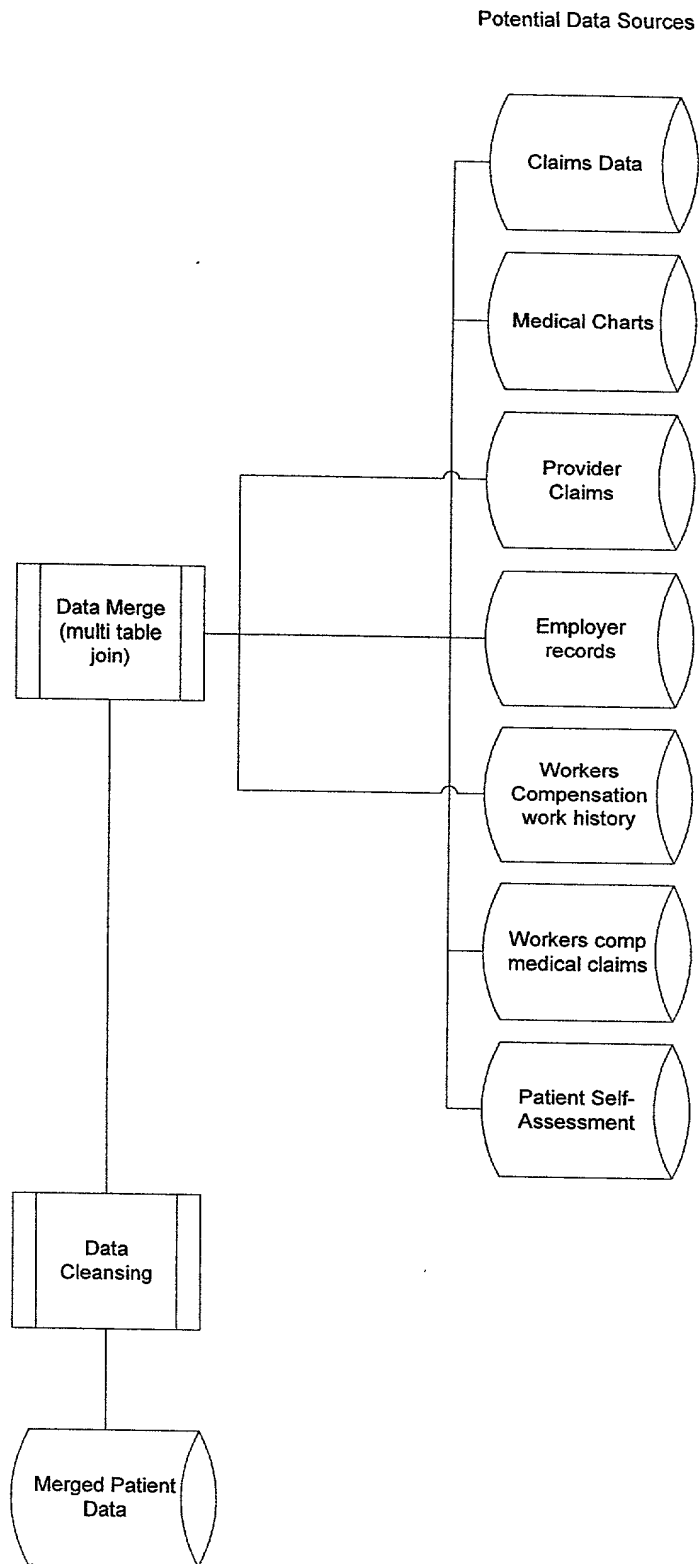


FIG. 9

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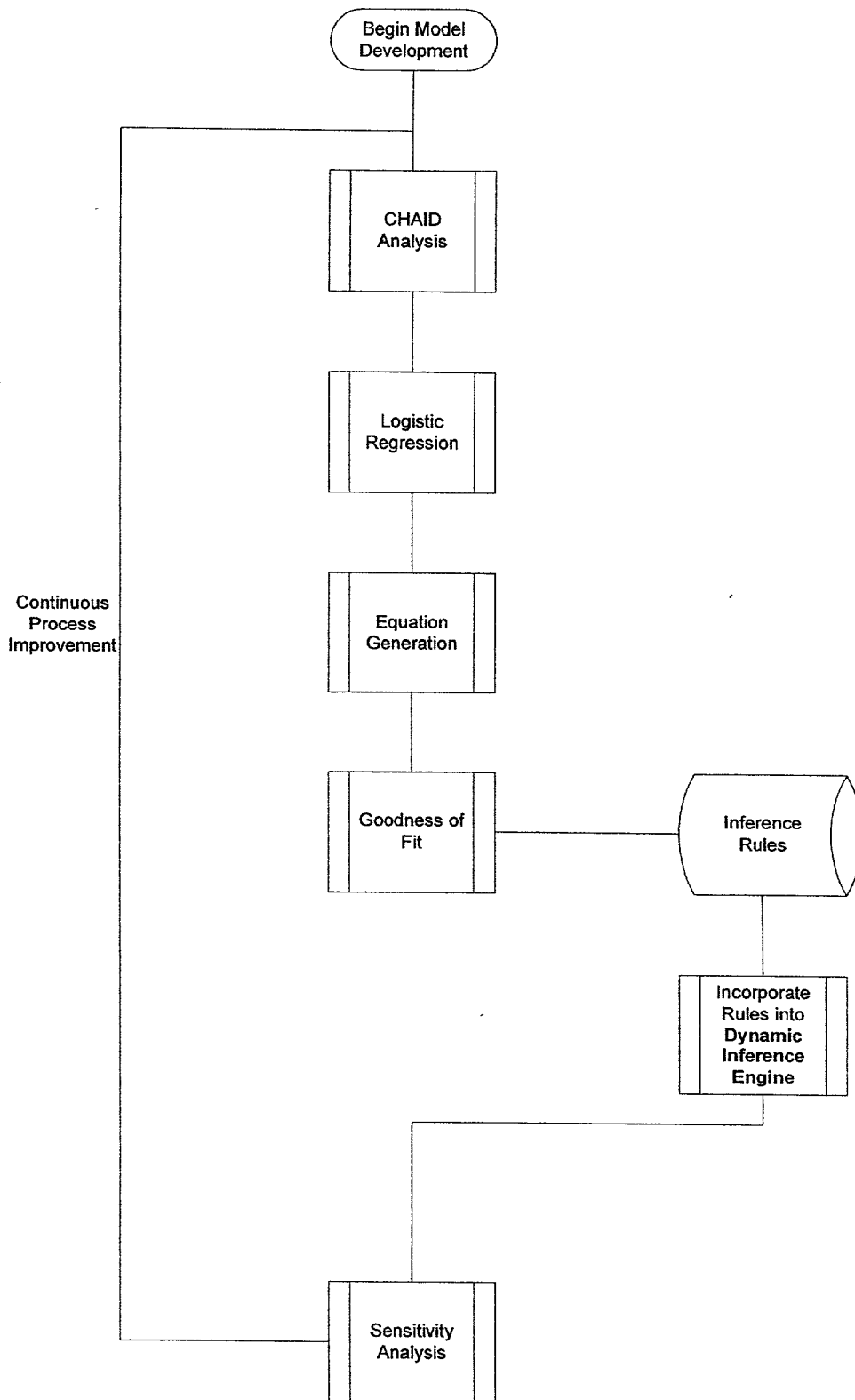


FIG. 10

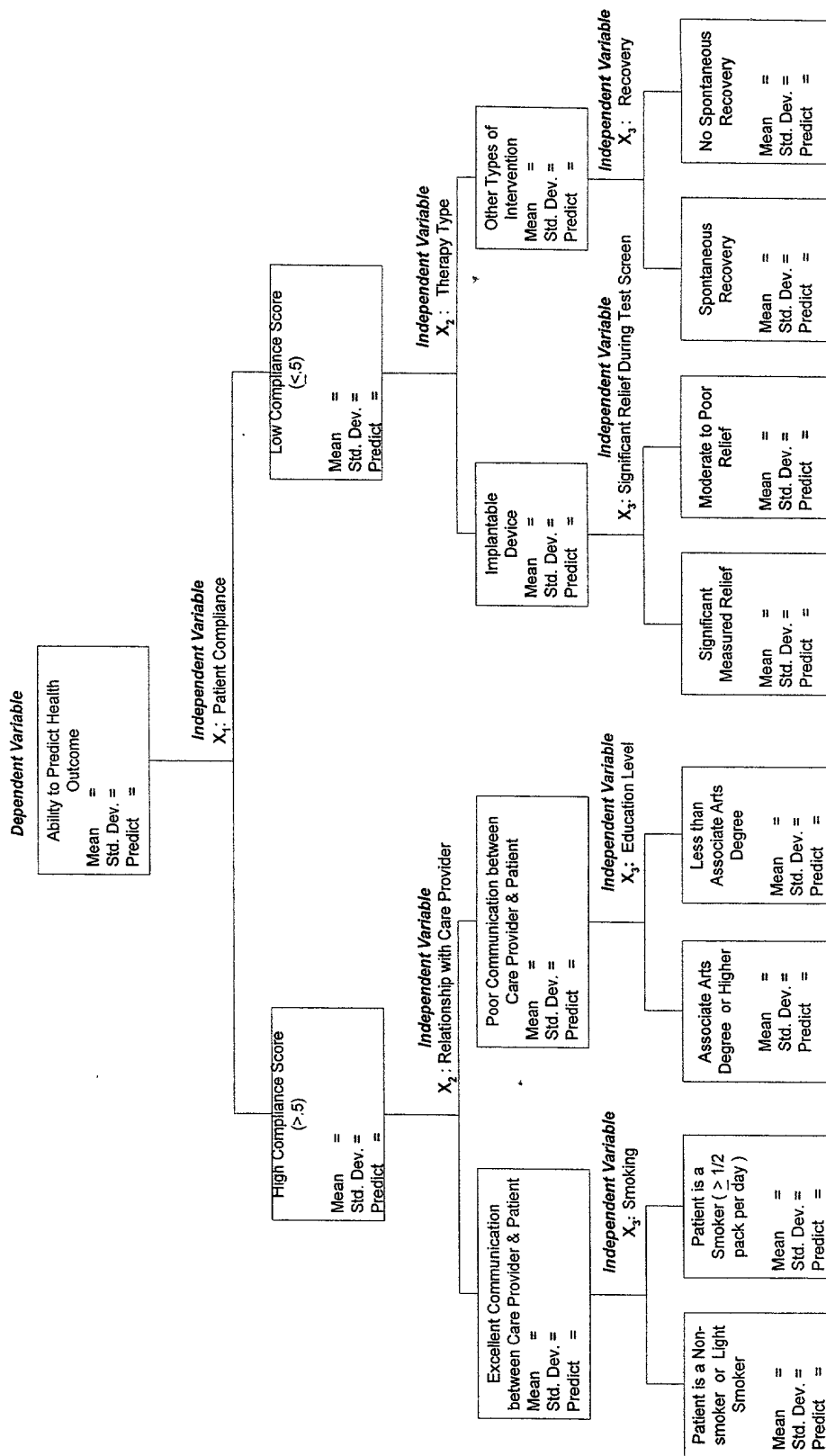


FIG. 11

Logistics Output Independent Variable	Variable Parameter	Odds Ratio	P-Value
Constant	(+)		
Number of Back Surgeries (X_1)	(+)	3.1	$P<0.05$
Mental Health (≥ 40 years) (X_2)	(+)	2.1	$P<0.05$
Job Type (X_3)	(+)	1.9	$P<0.05$
(X_4)			
(X_5)			

FIG. 12

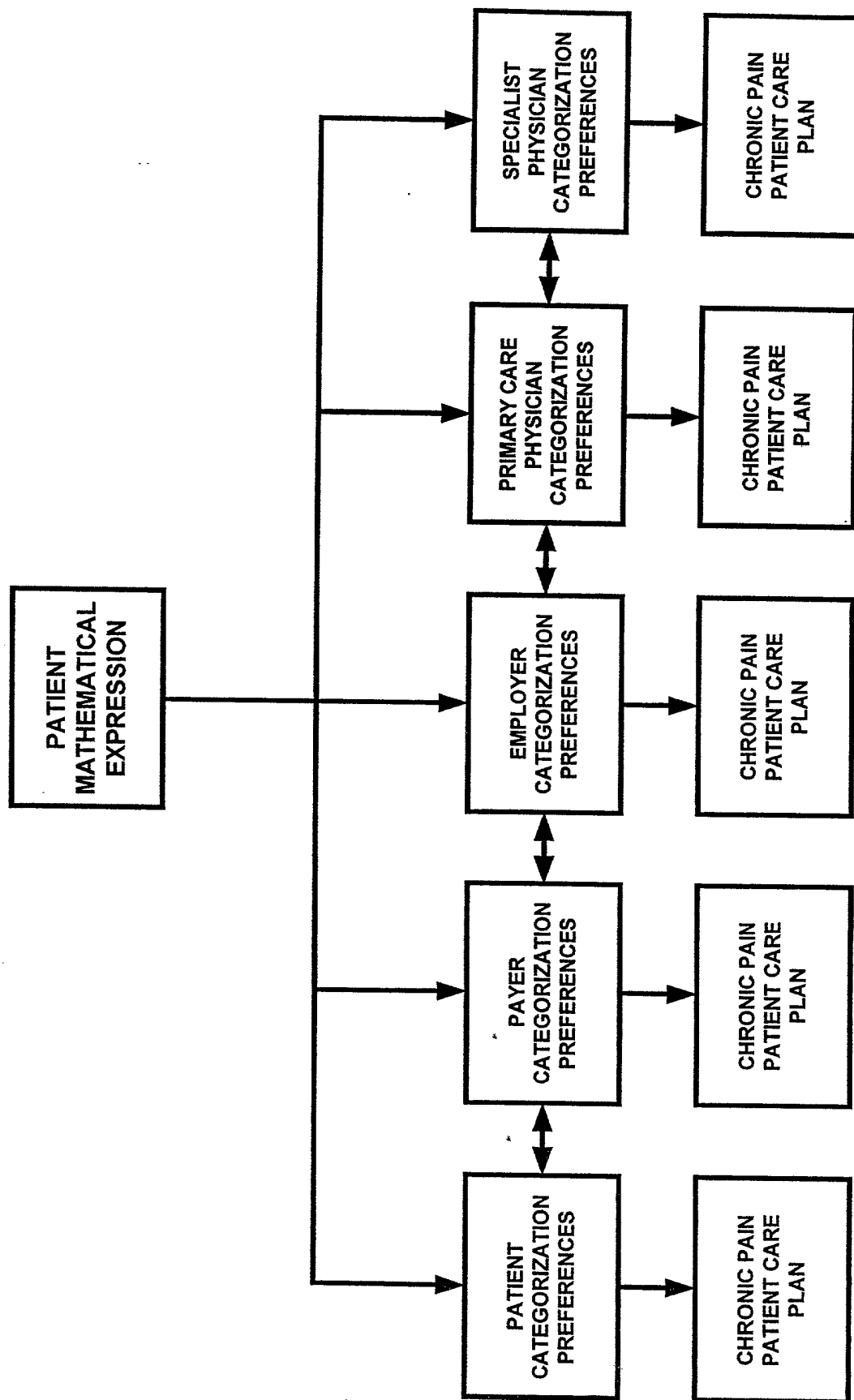


FIG. 13

Figure 1 consists of 12 sub-graphs (a-l) showing the time course of various physiological parameters during a 10-minute period. The parameters are: a) HR (b/min), b) BP (mmHg), c) SV (ml), d) CO (l/min), e) SVI (ml/m²), f) COI (l/min/m²), g) SVR (dyne/cm²), h) COI (l/min/m²), i) SVR (dyne/cm²), j) SVR (dyne/cm²), k) SVR (dyne/cm²), and l) SVR (dyne/cm²). Each graph shows a baseline period followed by a 10-minute intervention period. The y-axis for each graph is labeled with the parameter name and units. The x-axis is labeled 'Time (min)' with markers at 0, 5, and 10. The graphs show various trends: HR increases, BP decreases, SV increases, CO increases, SVI increases, COI increases, SVR decreases, and SVR increases.

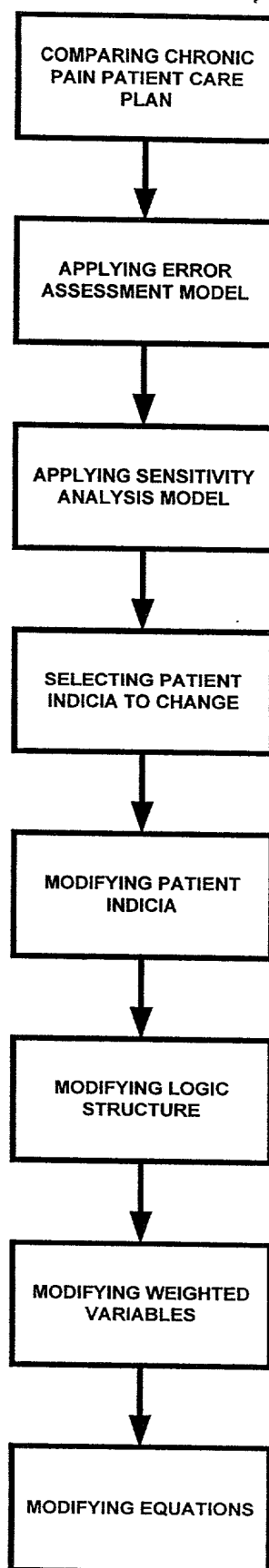


FIG. 14

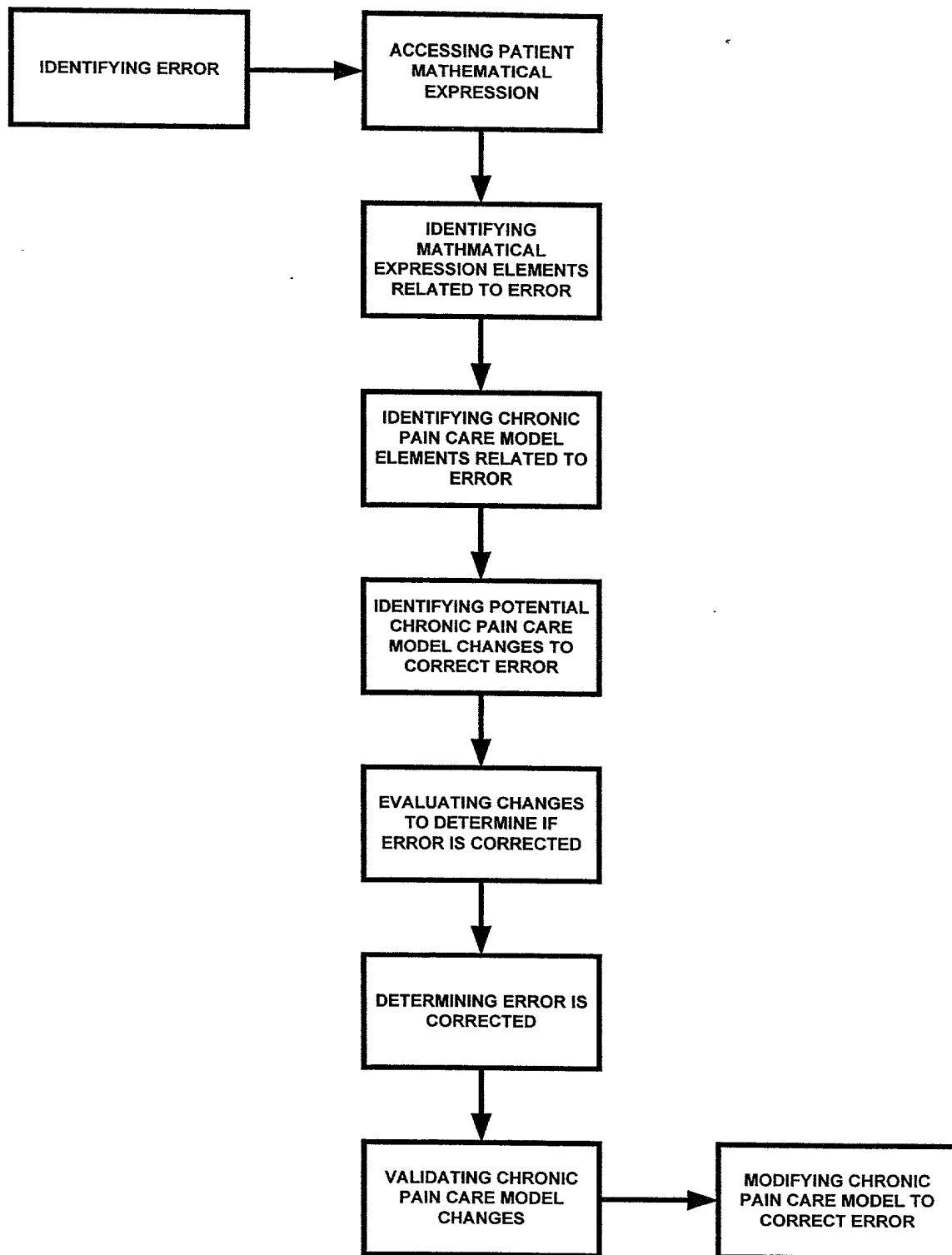


FIG. 15

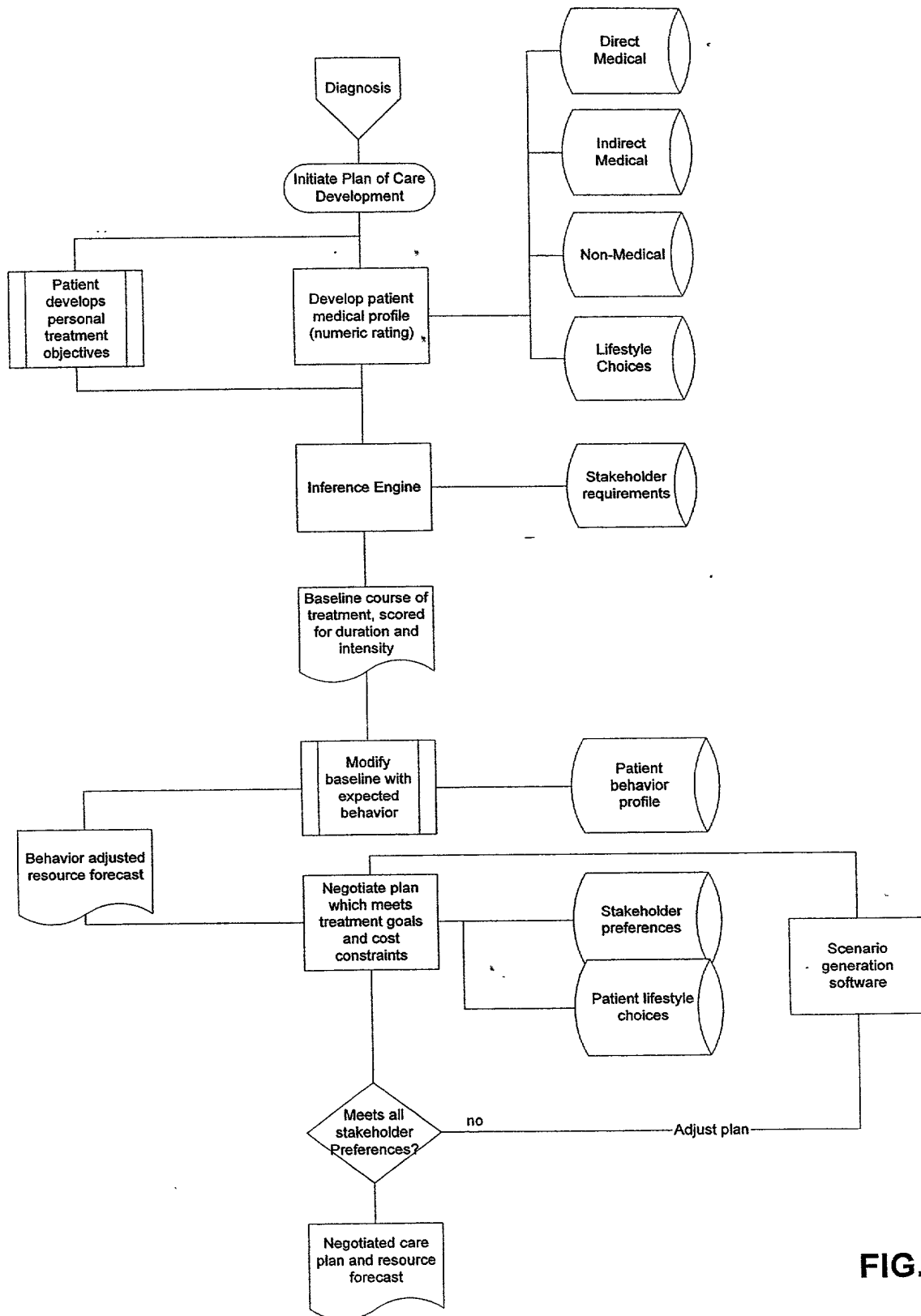


FIG. 16